

About Obesity and Current Treatment Options

Obesity Overview

Obesity Causes or Contributes to Serious Medical Conditions

Obesity is a global health problem affecting over 300 million people, according to the World Health Organization. Obesity causes or contributes to numerous serious medical conditions including type 2 diabetes, hypertension, cardiovascular disease, arthritis, sleep apnea, and certain types of cancer.

Studies have shown that significant weight loss may reduce or completely reverse these obesity-related diseases. Several major studies published in 2007 and 2008 demonstrated that weight loss surgery leads to improvements in life expectancy and may be significantly better than diet and conventional therapy in curing or improving diabetes.

The U.S. National Institutes of Health has published a guide on the identification, evaluation, and management of obesity in adults, including assessing risk related to various levels of obesity and recommending treatment (*The Practical Guide: Identification, Evaluation, and Treatment of Overweight and Obesity in Adults*. NIH Publication Number 00-4084. October 2000). Level of obesity is calculated using the body mass index, or BMI. Once a patient knows his or her BMI, they can determine the additional risk of disease and appropriate treatment options.

$$\text{BMI} = \text{Weight (kg)} / \text{Height (m}^2\text{)}$$

Classification of Overweight and Obesity by BMI, Waist Circumference and Associated Disease Risk*

	BMI (kg/m ²)	Obesity Class	Disease Risk* (Relative to Normal Weight and Waist Circumference)	
			Men ≤ 40 in (≤ 102 cm) Women ≤ 35 in (≤ 88 cm)	>40 in (> 102 cm) > 35 in (> 88 cm)
Underweight	< 18.5		–	–
Normal †	18.5 – 24.9		–	–
Overweight	25.0 – 29.9		Increased	High
Obesity	30.0 – 34.9	I	High	Very High
	35.0 – 39.9	II	Very High	Very High
Extreme Obesity	≥ 40	III	Extremely High	Extremely High

* Disease risk for type 2 diabetes, hypertension, and CVD

† Increased waist circumference can also be a marker for increased risk even in persons normal weight

Adapted from "Preventing and Managing the Global Epidemic of Obesity. Report of the World Health Organization Consultation of Obesity." WHO, Geneva, June 1997™

Source: *The Practical Guide: Identification, Evaluation, and Treatment of Overweight and Obesity in Adults*. NIH Publication Number 00-4084. October 2000.

Treatment options offered to patients start with conservative therapies such as diet and exercise, and progress to weight loss drugs or surgery depending on severity of obesity and obesity-related diseases. According to NIH, weight loss surgery is an option for patients with clinically severe obesity, i.e. a BMI > 40 or a BMI > 35 with comorbid conditions. Weight loss surgery should be reserved for patients in whom other methods of treatment have failed.

A Guide to Selecting Treatment

Treatment	BMI Category				
	25 – 26.9	27 – 29.9	30 – 34.9	35 – 39.9	≥ 40
Diet, physical activity, and behavior therapy	With Comorbidities	With Comorbidities	+	+	+
Pharmacotherapy		With Comorbidities	+	+	+
Surgery				With Comorbidities	+

Source: *The Practical Guide: Identification, Evaluation, and Treatment of Overweight and Obesity in Adults*. NIH Publication Number 00-4084. October 2000.

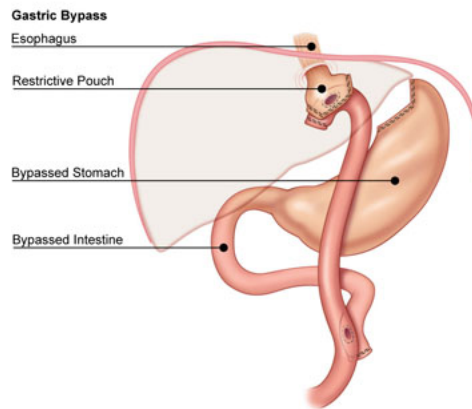
Treatment Options

For obese patients seeking treatment, there are multiple non-surgical and surgical treatment options. Non-surgical options include commercial weight loss programs (Weight Watchers, Jenny Craig), medically supervised weight loss programs, and drugs prescribed for weight loss. While these work for some patients, many patients have tried these options and failed. For these patients, surgery may be a consideration.

There are several surgical procedures that are commonly used to treat obesity. The two most common are gastric bypass and adjustable gastric banding. Both procedures are usually done through small incisions made in the abdominal wall (laparoscopically).

Gastric Bypass

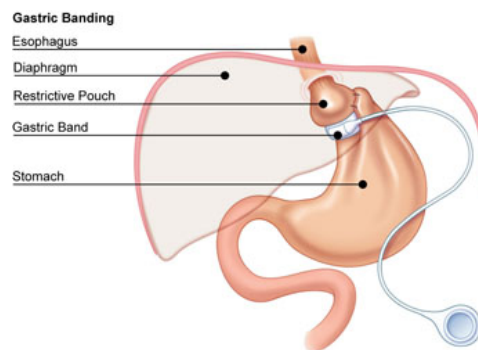
In gastric bypass, the surgeon uses a cutting stapler to create a small stomach pouch that can hold less food than the full stomach. Next a Y-shaped section of the small intestine is attached to the pouch to allow food to bypass the remainder of the stomach, the duodenum (the first segment of the small intestine), and the first portion of the jejunum (the second segment of the small intestine).



In this operation, the amount of food the patient can eat at one time is reduced (restriction), and the amount of calories absorbed by the body is reduced due to bypassing of the section of intestine (malabsorption). Weight loss with gastric bypass is excellent. With this type of operation most patients lose about 60 to 70 percent of their excess weight for 10 years or more. Complications of this procedure may occur in 5-15% of patients and may include infection, intestinal leaks or hernias. This type of operation may cause vitamin or calcium deficiencies due to the bypassing of a segment of intestine, so often patients have to take nutritional supplements. In addition, it can cause "dumping syndrome," where certain foods high in sugar cause the patient to have uncomfortable nausea, bloating and sometimes diarrhea.

Adjustable Gastric Bands

An adjustable gastric band is a silicone implant that the surgeon places around the stomach near its upper end. This creates a small pouch and a narrow passage into the rest of the stomach.



This small outlet delays the emptying of food from the pouch into the larger part of the stomach and causes a feeling of fullness after a small meal (restriction). The main advantages of this surgery are that there are fewer complications than with gastric bypass, and if necessary the band can be surgically removed. Complications of this procedure include surgical



infection, obstruction of the band opening, implant related infection or foreign body reactions, and longer-term issues such as band erosion or migration. While complications are less with this operation, patients who undergo adjustable gastric banding generally lose less weight than patients who have gastric bypass.

The U.S. National Institutes of Health (NIH) provide information on surgical treatments for obesity:

<http://win.niddk.nih.gov/publications/gastric.htm>

The TOGA® Procedure

The TOGA® Procedure is being developed and evaluated as a less invasive, incision-free procedure for obesity.

** Caution - The TOGA System is an investigational device, limited by U.S. law to investigational use. The TOGA System does not have the CE mark and is not approved for sale by any regulatory agency.